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Transmittal [1 page], Addendum to Supplemental Response to Office Action Mailed July 11, 2003 [2 pages], Reference – OSHA Section III Events Leading to the Final Standard [15 pages], and Reference – OSHA, Federal Registers, Respiratory Protection – 59:58884-58956 [1 page].

Applicant:	<u>Charles E. Loomis</u>	Group Art Unit:	<u>1732</u>
Serial No.:	<u>09/826,575</u>	Examiner:	<u>Michael T. Cygan</u>
Filing Date:	<u>04/05/2001</u>	Atty. Docket No.:	<u>P02054US1</u>
Title:	<u>Testing Apparatus and Method</u>		

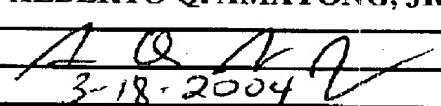
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TRANSMITTAL FORM <i>(to be used for all correspondence after initial filing)</i>	Application Number	09/826,575	
	Filing Date	04/05/2001	
	First Named Inventor	Loomis, et al.	
	Art Unit	1732	
	Examiner Name	Michael T. Cygan	
Total Number of Pages in This Submission	20	Attorney Docket Number	P02054US1

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<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input checked="" type="checkbox"/> Addendum to Supplemental Response <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation <input type="checkbox"/> Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____	<input type="checkbox"/> After Allowance communication to Group <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): 1) OSHA Ref. - Section III (15 pg); 2) OSHA Ref. - Federal Registers (1pg); 3) Cert. of Fax under 37 CFR 1.8
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Docket No.: P02054US1
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Charles E. Loomis, et al.

Application No.: 09/826,575

Group Art Unit: 1732

Filed: April 5, 2001

Examiner: Michael T. Cygan

For: TESTING APPARATUS AND METHOD

ADDENDUM TO THE SUPPLEMENTAL RESPONSE
TO OFFICE ACTION MAILED JULY 11, 2003

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This is an Addendum to the Supplemental Response to the Non-Final Office Action mailed July 11, 2003, which was transmitted by facsimile on March 17, 2004.

The documents listed below are discussed in the Supplemental Response and are provided herein for the Examiner's reference. These references are also being submitted in a Supplemental Information Disclosure Statement.

- 1) Occupational Safety & Health Administration (OSHA), Regulations (Preambles to Final Rules), Section 3 – III. Events Leading to the Final Standard; and
- 2) OSHA, Federal Registers, Respiratory Protection – 59:58884-58956, (first page only).

Application Serial No. 09/826,575

P02054US1

Applicants believe no additional fees are due with this submission. However, if an additional fee is due, please charge our Deposit Account No. 50-0997, under Order No. STDL-P02054US1 from which the undersigned is authorized to draw. Moreover, if any other Petition is required or if the appropriate Petition for Extension of Time does not accompany this Response, Applicants hereby apply for said Petition and authorize any fee associated therewith.

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The undersigned is available for consultation at any time, if the Examiner believes such consultation may expedite the resolution of any issues.

Dated: 03/18, 2004

Respectfully submitted,

By ALBERTO Q. AMATONG, JR.

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Section 3 - III. Events Leading to the Final Standard


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Regulations (Preambles to Final Rules)

Section 3 - III. Events Leading to the Final Standard

Regulations (Preambles to Final Rules) - Table of Contents

• Record Type:	Respiratory Protection
• Section:	3
• Title:	Section 3 - III. Events Leading to the Final Standard

III. Events Leading to the Final Standard

A. Regulatory History

Congress created the Occupational Safety and Health Administration (OSHA) in 1970, and gave it the responsibility for promulgating standards to protect the health and safety of American workers. As directed by Congress in the Occupational Safety and Health Act of 1970 (OSH Act; 29 U.S.C. 651 *et seq.*), OSHA adopted existing Federal standards and national consensus standards developed by various organizations such as the American Conference of Governmental Industrial Hygienists (ACGIH), the National Fire Protection Association (NFPA), and the American National Standards Institute (ANSI). The ANSI standard Z88.2-1969, "Practices for Respiratory Protection," is the basis of the first six sections of OSHA's previous standard, 29 CFR 1910.134, "Respiratory Protection." The seventh section was a direct, complete incorporation of ANSI Standard K13.1-1969, "Identification of Gas Mask Canisters." OSHA's previous construction industry standard for respiratory protection, 29 CFR 1926.103, was promulgated in April 1971. On February 9, 1979, 29 CFR 1910.134 was formally recognized as also being applicable to the construction industry (44 FR 8577). Until the adoption of these standards by OSHA, most guidance on respiratory protective device use in hazardous environments was advisory rather than mandatory.

OSHA's maritime standards were originally promulgated in the 1960s by agencies that preceded OSHA. The original OSHA code designations of these standards and their promulgation dates are: Shipyards -- 29 CFR 1915.82, February 20, 1960 (25 FR 1543); Marine Terminals -- 29 CFR 1917.82, March 27, 1964 (29 FR 4052); and Longshoring -- 29 CFR 1918.102, February 20, 1960 (25 FR 1565). Section 1910.134 was incorporated by reference into OSHA's Marine Terminals standard (part 1917) on July 5, 1983 (48 FR 30909). OSHA has recently updated and strengthened its Longshoring and Marine Terminal standards, and both standards incorporate 29 CFR 1910.134 by reference.

OSHA did not propose to expand coverage of 29 CFR 1910.134 to agricultural workplaces covered by 29 CFR part 1928, and this final Respiratory Protection standard, like the proposal, does not apply to agricultural operations. The prior standard likewise did not apply to agricultural operations. (See 29 CFR 1928.21.) OSHA received no public comment requesting a change in coverage. Accordingly, the issue of respirator use during agricultural operations was not a part of this rulemaking. OSHA notes, however, that respirator use during pesticide operations and handling is covered by EPA's Worker Protection Standard, 40 U.S.C. part 170, adopted under the authority of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (7 U.S.C. 136-136y).

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Under OSHA's previous standard, employers needed to follow the guidance of the Z88.2-1969 ANSI standard to ensure proper selection of respirators (see discussion 59 FR 58887). OSHA published an Advance Notice of Proposed Rulemaking (ANPR) to revise the respirator standard on May 14, 1982 (47 FR 20803). Part of the impetus for this notice was OSHA's inclusion of new respirator requirements in comprehensive substance-specific standards promulgated under section 6(b) of the Act, e.g., fit tests; use of powered air-purifying respirators (PAPRs) upon request; change of the filter elements of a respirator whenever an increase in breathing resistance is detected; employee permission to wash faces and respirator facepieces; and referral to a physician trained in pulmonary medicine for an employee who exhibits difficulty breathing, either at fit testing or during routine respirator use (see, e.g., 29 CFR 1910.1025 (lead standard)). The respirator provisions in these substance-specific standards took account of advances in respirator technology and changes in related guidance documents, particularly the recognition that standardized fit testing protocols greatly increase the effectiveness of respirators.

OSHA's 1982 ANPR sought information on the effectiveness of the current respiratory protection provisions, the need for revision of those provisions, and the substance of the revisions. Responses were received from 81 interested parties. The commenters generally supported revising OSHA's respiratory protection provisions and provided suggestions for approaches the Agency might take (Ex. 15).

On September 17, 1985, OSHA announced the availability of a preliminary draft of the proposed Respiratory Protection standard. The preproposal draft standard reflected the public comments received on the May 1982 ANPR, and OSHA's own analysis of changes needed in the standard to take into account the current state-of-the-art for respiratory protection. Responses were received from 56 interested parties (Ex. 36), and their comments were reviewed in preparing the proposal.

On November 15, 1994, OSHA published the proposed rule to revise 29 CFR 1910.134, and announced its intention to convene an informal public hearing on the proposal (59 FR 58884). The informal public hearing was convened on June 6, 1995, pursuant to notice and in accordance with Section 6(b) of the OSH Act, 29 U.S.C. 655(b)(3). Post-hearing submissions of data from parties at the hearing were received through September 20, 1995.

On November 7, 1995, OSHA reopened the record (60 FR 56127) and requested additional comment on a study performed for OSHA by Dr. Mark Nicas titled "The Analysis of Workplace Protection Factor Data and Derivation of Assigned Protection Factors." That study, which was placed in the rulemaking docket on September 20, 1995, addressed the use of statistical modeling for determining respirator APFs. Comments on the Nicas study were received through the end of January 1996. The Nicas report, and comments received in response to the November 1995 notice, have convinced OSHA to deliberate further on the complex issues surrounding the establishment of APFs.

The entire record including 200 exhibits, more than 3,000 individual items, and approximately 2,300 transcript pages, was certified by the presiding administrative law judge on June 30, 1997, in accordance with 29 CFR 1911.17. Copies of materials contained in the record may be obtained from the OSHA Docket Office, Room N-2439, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington, D.C. 20210; (202) 219-7894.

The final revisions to 29 CFR 1910.134 are based on consideration of the entire record of this proceeding, including materials discussed or relied upon in the proposal, the record of the informal hearing, and all written comments and exhibits received.

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B. Justification for Revising the Previous Standard**1. Purpose of the Revision**

The intent of this revision is to enhance the protection of worker health, promote more effective use of respirators, provide greater compliance flexibility, and clarify the policies and procedures employers must follow when implementing a respiratory protection program. Evidence in the record, including case reports and studies of respirator use among workers, indicates that selecting or using respirators improperly can result in employee illness and even death. (See discussion below.) The revised standard is therefore expected to reduce the number of occupational illnesses and deaths among workers who wear respirators. OSHA is also consolidating many of its respirator-related provisions in other substance-specific health standards into one standard to make these provisions easier for employers to administer. Through consolidation, repetitive and duplicative respirator requirements have been deleted from many existing OSHA health standards, and future health standards will reference the revised final rule for many respirator requirements.

Advances in technology also made the previous standard out-of-date in many areas. Nearly all rulemaking participants, including representatives of private industry, other Federal agencies, respirator manufacturers, and unions, agreed that revision is necessary to address these advances (e.g., NIOSH, Ex. 28; Eastman Chemical Co., Ex. 54-245; 3M, Ex. 54-218A; AFL-CIO, Ex. 54-315; Building and Construction Trades Department/AFL-CIO, Ex. 29; American Petroleum Institute, Ex. 37; ISEA, Ex. 54-363). (See also 59 FR 58889.) Other agencies and committees have already updated their guidance on respirator use. For example, the ANSI standard has been revised twice (Exs. 10, 50), and NIOSH has revised its certification standard (42 CFR part 84; 60 FR 30336; 6/8/95), as well as developed a Respiratory Decision Logic (1987) to provide guidance to employers on the selection of respirators.

OSHA's experience in enforcing the previous standard also indicated that some of that standard's requirements were not understood clearly by the regulated community, and so were not adequately effective in protecting workers. The clarifications in this new standard will contribute to enhanced compliance by reducing misinterpretations and inconsistencies. A review of OSHA enforcement data for 1994 and 1995 revealed that failure to comply with the previous standard was a critical factor in at least 47 fatalities and 126 catastrophic injuries. The most frequently cited deficiencies included failure to provide respirators at all or to have standard operating procedures governing respirator use, and failure to train or fit test respirator users adequately [Source: OSHA's Federal Inspection Compliance Data (IMIS; 10/92 to 12/95)].

In addition, considerable research has been performed to determine the extent to which respirators used in workplaces actually reduce the quantity of contaminant breathed by the respirator user. Researchers have compared the in-mask concentrations of contaminants to the concentration levels outside the masks. This work was begun by NIOSH during the mid-seventies to assess respirator effectiveness in coal mines and abrasive blasting operations (Ex. 64-5) and spray paint operations (Ex. 64-68). The studies assessed the effectiveness of respirators under various conditions, and measured employee exposure in situations when respirators were not worn. The effectiveness ratings obtained in these studies are usually termed "Effective Protection Factors" (EPF).

More recent studies by NIOSH and private researchers have monitored respirator use even more closely to isolate variables that may affect the levels of respirator performance. Many of these studies concerned the performance of powered air-purifying respirators (PAPRs),

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which were not achieving in workplaces the levels of performance that had been predicted based on laboratory tests (see, e.g., Exs. 64-46, 64-42, and 64-47).

A third group of studies, "workplace protection factor studies," conducted mostly by manufacturers and other private interests, was designed to determine the optimum performance of respirators by eliminating the impact of program defects under very tightly supervised workplace conditions. The results of these studies may overstate the degree of respirator effectiveness most employers can expect under conditions of workplace use because study conditions are rarely replicated in the field; nevertheless, these studies show the potential for respirators to reduce employee exposure to workplace contaminants (see, e.g., Exs. 64-25, 64-42, 64-47, 64-513).

This revised standard is intended to take account of up-to-date knowledge and technology and to make the requirements in the standard easier to understand. The standard now reflects current technology and research, as well as the findings and guidance of other expert bodies. OSHA has also included a new definitions section to enhance clarity. The revised standard includes detailed protocols for performing fit tests and lists the topics in which respirator users must be trained. It also contains provisions addressing skin and eye irritation, both of which must be considered in respirator selection. Wherever possible, OSHA has used performance-oriented language to allow for flexibility in accommodating future changes in respirator technology and to address the needs of small businesses and unusual operations. Through these improvements, OSHA expects to reduce the number of respirator-related illnesses, fatalities, and catastrophic injuries occurring among respirator wearers in U.S. workplaces.

2. Respirator Use and Hazards

The purpose of a respirator is to prevent the inhalation of harmful airborne substances or oxygen-deficient air. Basically, a respirator is an enclosure that covers the nose and mouth or the entire face or head. Respirators are of two general "fit" types: (1) Tight-fitting (quarter masks, which cover the mouth and nose; half masks, which fit over the nose and under the chin; and full facepiece, which cover the face from the hairline to below the chin); and (2) loose-fitting (hoods, helmets, blouses, or full suits which cover the head completely). There are also two major classes of respirators: air-purifying respirators (which remove contaminants from the air), and atmosphere-supplying respirators (which provide clean breathing air from an uncontaminated source). In general, atmosphere-supplying respirators are used for more hazardous exposures.

Effective respirator use can protect employees from exposure to a wide variety of toxic chemicals. In 1994, approximately 215 deaths, or five percent of all workplace fatalities, occurred as a result of exposure to harmful substances and environments [CFOI, BLS, 6/11/96; CFOI/FAX]. There are a number of workplace situations that involve toxic substances and for which engineering controls may be inadequate to control exposures, and respirators are used in these situations as a back-up method of protection. Substances that have been associated with death or serious incidents include carbon monoxide, trichloroethylene, carbon dioxide, chromic acid, coal tar, several toxic metal fumes and dusts, sulphur dioxide, wood dust, and welding fumes; these substances cause adverse health effects ranging from transient, reversible effects such as irritation or narcosis, through disabling diseases such as silicosis and asbestosis, to death caused either by acute exposure or by a cancer resulting from chronic exposures (Rom, W., *Environmental and Occupational Medicine*, 2nd ed., Little, Brown & Co., Boston; 1992, p. 598.) Respirators are available that can provide protection against inhalation of these toxic substances.

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Airborne contaminants may also be radioactive ("Radiologic Health in Occupational Medicine Practice," George L. Voelz, pg. 500 in *Occupational Medicine*, Carl Zenz, ed., Year Book Medical Publishers, Inc., Chicago, 1975; Jacob Shapiro, *Radiation Protection*, 3rd ed., Harvard University Press, Cambridge, MA, 1990, pg. 273). (See also 29 CFR 1910.1096.) Exposure to ionizing radiation can cause acute effects such as nausea and vomiting, malaise and fatigue, increased temperature, and blood changes. More severe delayed effects include leukemia, bone and lung cancer, sterility, chromosomal and teratogenic damage, shortened life span, cataracts, and radiodermatitis, a dry, hairless, red, atrophic skin condition which can include skin cracking and depigmentation (George L. Voelz, M.D., "Radiologic Health in Occupational Medicine Practice", in Zenz, *Occupational Medicine*, pp. 513-519; Herman Cember, *Introduction to Health Physics*, 2nd edition, Pergamon Press, New York, 1983, pg. 181-194). Respirators to provide protection against the inhalation of radioactive particles are commonly used by workers exposed to these hazards.

"Bioaerosols" are airborne contaminants that are alive or were released from a living organism (OSHA Docket No. H-122; ACGIH Guidelines; Ex. 3-61C, page 1; 1994). Pulmonary effects associated with exposure to certain bioaerosols include rhinitis, asthma, allergies, hypersensitivity diseases, humidifier fever, and epidemics of infections including colds, viruses, tuberculosis, and Legionnaires Disease. Cardiovascular effects manifested as chest pain, and nervous system effects manifested as headache, blurred vision, and impaired judgment, have occurred in susceptible people following exposure to bioaerosols. Viral infections caused by the inhalation of bioaerosols can result in health effects that range in intensity from undetected or mild to more severe and even death. Bacterial infections resulting from inhalation of bacteria and their products cause a range of diseases, including tuberculosis, Legionnaires Disease, and hypersensitivity pneumonitis. Among workers in sewage treatment plants, health-related problems can be associated with occupational exposures to protozoa [Burge, H., 1990, "Bioaerosols: Prevalence and health effects in the indoor environment," *J. Allergy and Clinical Immunology*; 86 (5); see also Exs. 3-61B and 3-61C in Docket No. H-122.] Allergic asthma and allergic rhinitis can be induced by chronic exposure to low levels of antigens. Hypersensitivity pneumonitis can occur when a worker inhales concentrated aerosols of particles released by bacteria, fungi, and protozoa (Exs. 3-61B and 3-61C in Docket No. H-122). In 1994, the Centers for Disease Control reported 41 deaths of workers for which there was evidence of work-related hypersensitivity pneumonitis (*Work-Related Lung Disease Surveillance Report*, 1994; USDHHS, CDC, DHHS (NIOSH) Number 94-120). Respirators to protect against the inhalation of biological agents are widely used in healthcare and other workplace settings where exposure to such agents presents a hazard to workers.

Respirators can also provide protection from oxygen-deficient atmospheres. Human beings must breathe oxygen in order to survive, and begin to suffer adverse health effects when the oxygen level of their breathing air drops below the normal atmospheric level. Below 19.5 percent oxygen by volume, air is considered oxygen-deficient. At concentrations of 16 to 19.5 percent, workers engaged in any form of exertion can rapidly become symptomatic as their tissues fail to obtain the oxygen necessary to function properly (Rom, W., *Env. Occup. Med.*, 2nd ed; Little, Brown; Boston, 1992). Increased breathing rates, accelerated heartbeat, and impaired thinking or coordination occur more quickly in an oxygen-deficient environment. Even a momentary loss of coordination may be devastating to a worker if it occurs while the worker is performing a potentially dangerous activity, such as climbing a ladder. Concentrations of 12 to 16 percent oxygen cause tachypnea (increased breathing rates), tachycardia (accelerated heartbeat), and impaired attention, thinking, and coordination (e.g., Ex. 25-4), even in people who are resting.

At oxygen levels of 10 to 14 percent, faulty judgment, intermittent respiration, and

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exhaustion can be expected even with minimal exertion (Exs. 25-4 and 150). Breathing air containing 6 to 10 percent oxygen results in nausea, vomiting, lethargic movements, and perhaps unconsciousness. Breathing air containing less than 6 percent oxygen produces convulsions, then apnea (cessation of breathing), followed by cardiac standstill. These symptoms occur immediately. Even if a worker survives the hypoxic insult, organs may show evidence of hypoxic damage, which may be irreversible (Exs. 25-4 and 150; also reported in: Rom, W., *Environmental and Occupational Medicine*, 2nd ed; Little, Brown; Boston, 1992).

A number of workplace conditions can lead to oxygen deficiency. Simple asphyxiants, or gases that are physiologically inert, can cause asphyxiation when present in high enough concentrations to lower the oxygen content in the air. Other toxic or chemical asphyxiants poison hemoglobin, cytochromes, or other enzyme systems (Rom, W., *Environmental and Occupational Medicine*, 2nd ed., Little, Brown, and Co., Boston, 1992). A number of asphyxiants are gases that can evolve from explosions, combustion, chemical reactions, or heating. A high-temperature electrical fire or arc welding accident causing a complete flashover in an enclosed area can temporarily eliminate oxygen from that area. Asphyxiation and the severe lung damage it can cause are major concerns for firefighters; of 30 firefighter deaths investigated by OSHA recently, five resulted from either asphyxiation, smoke inhalation, or flashovers (IMIS; 8 State plan states; 10/91-3/97). (See also mortality study of causes of death among firefighters, Guidotti, 37 *JOEM* 1348, 1995.)

In 1994, 110 employees died from oxygen deficiency [National Census of Fatal Occupational Injuries (CFOI); BLS; CFOI/FAX; 6/11/96)], i.e., about two percent of the total number of employees who died of occupational injuries. OSHA believes that many of these deaths could have been prevented if the victims' employers had realized that respirators were needed (BLS; CFOI/FAX, 6/96).

In some cases, respirator use itself can cause illness and injury to employees. There are a number of physiological burdens that are associated with the use of certain types of respirators. The weight of the respirator, breathing resistances during both normal operation and if the air-purifying element is overloaded, and rebreathing exhaled air from respirator "dead space" can all increase the physiologic burden of respirator use (Exs. 113, 22-1, 64-427). Job and workplace conditions, such as the length of time a respirator must be worn, the level of physical exertion required of a respirator user, and environmental conditions, can also affect the physiological burden (Exs. 113, 64-363). In addition, workers who wear glasses or hearing aids may have problems achieving appropriate fit with some respirator facepieces.

Evidence of Adverse Health Effects From Respiratory Hazards. There is ample evidence that the previous standard was not doing an adequate job of protecting workers from these respiratory hazards, and that exposure to these hazards has continued to cause adverse health effects among exposed workers. An analysis of OSHA inspection data from 1976 through 1982, when the previous standard had been in effect for between five and eleven years (Ex. 33-5), found that in most cases (55.6%) where respirators were used to protect employees from excessive levels of air contaminants, respiratory protection programs were deficient in one or more elements, thus increasing the potential for employee exposure. Even more significant was the fact that in 72.1% of inspections in which an overexposure to a substance listed under 29 CFR 1910.1000 was cited, respirator use did not comply with the respiratory protection standard. OSHA performed a similar analysis of enforcement data for 1990-1996, and found similar levels of noncompliance. [See also *Work-Related Lung Disease Surveillance Report*, 1994; USDHHS, CDC, DHHS (NIOSH) Number 94-120.] The provisions of the new respirator standard are designed to regulate how an employer selects,

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maintains, fit tests, and trains employees in the proper use of respiratory equipment, and to provide employers with the tools needed to implement an effective respiratory protection program. OSHA has concluded that the new standard will eliminate many of the unnecessary illnesses and deaths described in this section.

C. Responses to Advisory Committee on Construction Safety and Health

The revised respirator standard replaces the previous respiratory protection standard in the construction industry (29 CFR 1926.103). Since this revision affects the construction industry, the September 1985 preproposal draft standard was presented to the Advisory Committee for Construction Safety and Health (ACCSH) for its comments. The ACCSH comments, combined with the other comments received, were considered in preparing a revision of the September 1985 draft proposal.

As part of the Notice of Proposed Rulemaking (NPRM) approval process, the revised NPRM was presented at the March 1987 ACCSH meeting and the Committee's comments were presented to OSHA at the August 1987 meeting (Ex. 39). OSHA responded to the Committee's comments in the NPRM, published in November, 1994. As noted in that response, OSHA modified the draft proposal to respond to the concerns of the Committee (59 FR 58931-58935).

The final standard replaces the previous construction industry standard for respiratory protection, 29 CFR 1926.103, with an amended 29 CFR 1926.103. The provisions of the previous respiratory protection standard (29 CFR 1926.103) are deleted by this action. The title, Respiratory Protection, will remain in the Code of Federal Regulations but will now be followed by the statement "Respiratory protection for construction employment is covered by 29 CFR 1910.134." The full text of this new standard will be printed in the general industry standards, and the construction standard will reference the revised 29 CFR 1910.134.

The Agency's responses to the Committee's specific concerns follow:

Paragraph (a) -- Permissible Practice

The Construction Advisory Committee recommended that paragraph (a)(1) of the standard be changed to require that all feasible engineering controls be used by employers and that the employer demonstrate that engineering controls are not feasible before respirators may be used. The recommended change also would have eliminated the requirement that appropriate respirators be used while engineering controls are being installed. OSHA has stated elsewhere in the summary and explanation section of this preamble that paragraph (a)(1) of the previous standard remains unchanged in the new final standard because this paragraph was not proposed for revision and was therefore not a subject of rulemaking in this proceeding. The purpose of the Respiratory Protection standard is to improve the level of protection provided to employees who use respirators to protect them from respiratory hazards, regardless of whether that use occurs in an environment where engineering controls are in place.

The Committee proposed that paragraph (a)(2) be modified to require that employers provide respirators to employees exposed to contaminant concentrations when the concentration reaches one-half the PEL or TLV, and that employees be required to wear them before the PEL is exceeded. To accompany this revision the Committee proposed a new definition establishing an "action level" of one-half the PEL for all regulated substances. OSHA has not adopted this ACCSH recommendation because the recommended changes are beyond the scope of this rulemaking.

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Paragraph (b) -- Definitions

ACCSH suggested that OSHA add a definition for "Grade D breathing air" to the standard. The properties of Grade D breathing air are listed in paragraph (i) of the final standard, Supplied Air Quality and Use. OSHA believes that repeating these elements in the definition section is redundant and unnecessary.

The Committee also recommended that the rule include a definition for "competent person," as defined in 29 CFR 1926.32(f). The competent person would review the respiratory protection program and perform the function of the respiratory program administrator required in paragraph (c)(2) of the proposal. OSHA has not included a definition of competent person in the standard because 29 CFR 1926.32(f) already has such a definition. OSHA recognizes, however, that, in construction settings, the competent person is often also the administrator of the respirator program.

The Committee also recommended that the NIOSH Recommended Exposure Limits (RELs) be used along with the TLVs, to define a hazardous exposure level in the absence of a PEL. This point is no longer relevant because the concept of "hazardous exposure level" is not included in the final respiratory protection standard.

The proposal would have limited the use of air-purifying respirators for hazardous chemicals with poor or inadequate warning properties. ACCSH recommended a change to the definitions of "inadequate warning properties" and that OSHA add a new definition for "odor threshold." Because the final standard takes a different approach to determining when air-purifying respirators are appropriate, OSHA has not adopted the changes recommended by ACCSH.

ACCSH also suggested that OSHA revise the proposed definition of maximum use concentration (MUC). In the final standard the definition of MUC has been reserved, pending completion of a subsequent stage of this rulemaking that will concentrate on establishing OSHA Assigned Protection Factors (APFs).

The Construction Advisory Committee also recommended replacing the proposal's definition of "respirator;" because the final standard contains no definition of "respirator," this suggestion has not been adopted. The Committee also recommended revising the proposed definition of "service life." However, since OSHA's definition of this term has been broadened in the final rule and the rule contains detailed requirements for change schedules for cartridges and canisters, ACCSH's concerns have largely been addressed.

Paragraph (c) -- Respirator Program

Paragraph (c)(1) of the proposal contained a requirement that the employer establish a respirator program that "covers" certain elements, as applicable. OSHA has followed the Committee's recommendation that OSHA change the word "cover" to "include" but not removed the phrase "as applicable," as recommended by the Committee, because not all elements of the program apply in all situations, and thus the "as applicable" language is appropriate.

The Committee also recommended that OSHA add an element to the written respirator program on procedures for monitoring the work environment, using monitoring results when selecting respirators, and selecting the most protective respirators in situations where monitoring cannot be performed (as is often the case in construction). OSHA considered this comment in drafting the final standard, which permits the employer to make reasonable

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estimates of exposure as part of the respirator selection process. In most cases, as discussed in the summary and explanation of paragraph (d), monitoring results will form the basis of a reasonable estimate. Where the employer cannot estimate exposure, the atmosphere must be considered immediately dangerous to life or health (IDLH). For IDLH atmospheres, the most protective respirators are required.

One of the elements in the written respirator program, paragraph (c)(1)(vi), states that the program shall include procedures to ensure proper air quality for atmosphere-supplying respirators. ACCSH asked OSHA to add the words "quantity and flow" to provide more direction for employers on what the procedures should cover. OSHA agrees and has revised the wording of this element accordingly.

ACCSH recommended that OSHA substitute the term "competent person" in paragraph (c)(2) for the language "person qualified by appropriate training and/or experience." This recommendation has already been discussed above, in connection with ACCSH's comments on paragraph (b).

The written respiratory protection program, in paragraph (c)(3), is required to reflect current workplace conditions and respirator use. The Committee urged OSHA to add the term "training" to this element. OSHA has not done so because training is addressed in another program element. The Committee also recommended that OSHA add to paragraph (c) a provision allowing employees and designated representatives access to exposure and medical records maintained by the employer. Because this requirement is already included in 29 CFR 1910.1020, the medical and exposure records access standard, and referenced in this final respiratory protection standard, the Agency has not done so.

Proposed paragraph (c)(5) required employers to make the written program available to affected employees, designated representatives, and OSHA. The Committee requested that employers be required to send a copy of the program to the OSHA Special Assistant for Construction. However, the proposed requirement has been moved to paragraph (m) of the final standard, which requires that all written materials maintained under the standard be made available upon request to affected employees and the Assistant Secretary. This requirement should meet any need that may arise for copies of the written program.

The Committee further recommended that the written respirator program be maintained and made available to employees at the job site, and that the medical and monitoring results pertaining to respirator use be available at the work site as well. The final standard in paragraph (m) now requires employers to allow employees to examine and copy written programs upon request. Access to medical and monitoring records for employees exposed to toxic substances or harmful physical agents is regulated by OSHA in a separate standard, 29 CFR 1910.1020. That standard applies to construction workplaces as well as general industry workplaces and requires the employer to ensure that access to medical and monitoring records is provided in a reasonable time, place, and manner (1910.1020(e)(1)(i)). Nothing in the final respiratory protection standard is intended to alter this requirement.

Paragraph (d) -- Selection of Respirators

In its review of paragraph (d) of the proposal on selection of respirators, the Committee requested OSHA to add a new provision that would require monitoring for contaminants when air-purifying respirators are used. This request is related to the recommendation for mandatory monitoring, discussed above. The final standard requires that employers make reasonable estimates of employee exposure levels when selecting all respirators, not just air-purifying ones. Even if current monitoring results are unavailable, employers must base their

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exposure estimates on reliable data, which might include, for example, the results of past monitoring for similar construction jobs. Extensive discussion of this issue is contained in the summary and explanation section of this preamble for paragraph (d). OSHA believes that allowing exposure estimates that may be based on past monitoring and other representative data makes sense for the construction industry, where jobs are often short-lived and current monitoring data relating to specific employees/operations may not be available when respirators must be selected. Because the final standard allows employers to rely on reasonable estimates of exposure as well as monitoring results, OSHA has not added a requirement to the standard mandating that employers "obtain" needed information, as recommended by the Committee.

The Committee also recommended removal of the proposed phrase "when they exist" to modify the requirement that employers select only NIOSH-approved respirators. Instead, the Committee recommended use of the most protective respirator available, an SCBA or supplied air respirator, in cases where no approved air-purifying respirator exists. OSHA has removed the phrase "when they exist" from the final standard, for reasons explained in the summary and explanation discussion relating to paragraph (d).

The Committee urged OSHA to include poor odor warning properties as a reason for prohibiting the use of air-purifying respirators, and to remove proposed paragraph (d)(6)(ii), which, under limited circumstances, would have allowed their use with substances with poor odor warning properties. Final paragraph (d)(3) modifies the proposal, and places many limitations on air-purifying respirator use with gases and vapors, regardless of the existence of warning properties.

The Committee objected to the use of air-purifying respirators in an atmosphere with an oxygen content of 19.5 percent at altitudes of 14,000 feet or below; in the Committee's view, supplied air respirators should be required in this situation. OSHA continues to treat atmospheres at altitudes of 14,000 feet or below that have oxygen concentrations of at least 19.5% as non-oxygen-deficient, and to require atmosphere-supplying respirators in these atmospheres. OSHA's reasons for this determination are detailed in the summary and explanation section for paragraph (d).

Paragraph (e) -- Medical Evaluations

The Committee recommended that a mandatory medical examination be required in accordance with ANSI Z88.2, and that the standard include a list of diseases and conditions that should be considered in determining an individual's ability to wear a respirator. The final standard allows employers to rely on a screening questionnaire to identify employees with specified conditions that will require follow-up medical examinations. The questionnaire specifies medical conditions that OSHA has determined often relate to an employee's ability to use a respirator. OSHA believes that this provision responds to the Committee's concern.

Based on the comments of ACCSH and others, OSHA has decided to eliminate the proposed exemption for employees wearing respirators for no more than 5 hours per week, for the reasons explained below in the Summary and Explanation. The final rule also reflects the Committee's recommendation that the medical opinion provided to the employer include only limitations on the employee's ability to use a respirator.

The Committee recommended that OSHA add a provision to this paragraph requiring the employer to inform the person performing the medical examination of the atmospheric contaminants to which the employee would be exposed. The final standard meets this concern by requiring that the physician or other licensed health care professional (PLHCP)

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receive a copy of the employer's written respirator program, and information about other environmental conditions an employee may encounter; this information will allow the medical professional to judge whether the employee is medically capable of wearing the respirator.

The final rule allows an employer who has, within the preceding 12 months, provided his or her employees with a medical evaluation that fulfills the requirements of the revised standard to rely on the results of that evaluation. OSHA believes that this provision is responsive to the Committee's concern that limitations be placed on the "portability" of medical evaluations.

The Committee recommended that OSHA add a new provision to paragraph (e) to require that the employer provide a powered air- purifying respirator or atmosphere-supplying respirator to any employee found medically unable to wear a negative pressure respirator but otherwise able to perform the task to be done. The final standard requires the employer to provide a PAPR to an employee when the PLHCP informs the employer that the employee has a medical condition that may place the employee's health at increased risk of material impairment if the employee uses a negative pressure respirator (paragraph (e)(6)(ii)) and is thus responsive to the Committee's concern.

Paragraph (f) -- Fit Testing

With respect to fit testing procedures, the Committee recommended that proposed paragraph (f)(1) be rewritten to state that respirators must fit the employee so as to ensure that no exposure above the TLV or ceiling level occurs. OSHA agrees with the Committee's emphasis on fit testing and believes that the final rule's fit testing requirements and the fit test protocols in an appendix to the standard will ensure that employees are protected from the overexposures of concern to the Committee.

The Committee also suggested clarifying that a fit test is required whenever a different make or size respirator is used or when the facial characteristics of the employee change. The final rule addresses both of these points.

The Committee recommended limiting the fit testing requirements to tight-fitting negative pressure respirators. This issue, and OSHA's reasons for requiring fit testing of all tight-fitting respirators, is discussed in the fit testing section of the Summary and Explanation. OSHA has also deleted the proposed provision, objected to by the Committee, that would have allowed the employer to use a qualitative fit test for selecting respirators for employees who require fit factors greater than 10 in situations where outside contractors who do the quantitative fit testing are not available.

Paragraph (g) -- Respirator Use

Paragraph (g)(1) of the final standard adopts the proposed provision prohibiting the use of respirators that rely on a tight facepiece fit when facial conditions such as a beard or scarring would prevent such fits. The Committee urged OSHA to extend this provision to cover loose-fitting respirators as well as tight-fitting ones. OSHA explains in the Summary and Explanation for this paragraph that conditions such as a beard or facial scarring would have no effect on the performance of loose-fitting hoods or helmets, and OSHA therefore does not regard it as appropriate to make this change.

Employees who wear glasses were required in proposed paragraph (g)(4) to wear them in a manner that does not interfere with the facepiece seal of the respirator. The final standard

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continues this requirement (paragraph (g)(1)(ii)). The Committee suggested an additional requirement stating that, where the employee must wear corrective lenses and the respirator requires that these be of special design, the employer provide the lenses at no cost to the employee. OSHA believes, however, that such a requirement is not necessary because, in most cases where negative pressure respirators may be worn, half-masks are acceptable, and half-masks eliminate the concern about corrective glasses interfering with facepiece seal. Because the final standard allows contact lenses to be worn, full facepiece respirators can be worn by persons needing corrective lenses; contact lenses obviously do not interfere with facepiece seal. Thus, the final rule gives employers several options for addressing this concern of the Committee's.

Paragraph (h) -- Maintenance and Care of Respirators

The Committee urged OSHA to add the phrase "on paid time" to this paragraph to ensure that employers not require employees to clean their respirators on their own time. OSHA has decided in the final rule simply to require employers to ensure that respirators are cleaned according to mandatory procedures or their equivalents. OSHA believes that this approach is appropriate because the record demonstrates that on-site, employer-supervised cleaning is the prevalent cleaning procedure and the standard's rigorous requirements for cleaning respirators will limit off-site cleaning of respirators by employees.

Paragraph (k) -- Training

The training section of the proposal would have required that employers provide a training program for employees who are required to wear respirators. The Committee urged OSHA to add language to paragraph (k)(1) to require employers to provide, conduct and document the effectiveness of the training program. The final standard takes a more integrated approach in that it requires employers to evaluate the entire respiratory protection program rather than the training program specifically.

Paragraph (m) -- Recordkeeping

OSHA has adopted the Committee's recommendation to add the phrase "and make available" to proposed paragraph (m)(1)(iii), which required employers to maintain records of medical evaluations in accordance with 29 CFR 1910.1020, the Access to Employee Exposure and Medical Records standard (see paragraph (n)(1) of the final rule).

Appendix B -- Recommended Practices

Appendix B-1 of the standard contains practices for performing positive and negative pressure facesal checks. Respirator wearers are required by paragraph (g)(iii) to perform a facesal check before entering the work area either by following the mandatory facesal check methods in Appendix B-1 or by following the respirator manufacturer's recommended method, if the employer shows that the manufacturer's method is as effective as the required methods. The Committee urged OSHA to add new fit check methods to Appendix B-1, and OSHA has responded to this recommendation by allowing the methods suggested by the Committee if they are as effective as the methods in the Appendix.

ACCSH also recommended that OSHA issue a separate respirator standard for the construction industry. OSHA has reviewed the Committee's comments to identify which construction-specific concerns call for provisions that differ from those applicable to general industry. First, many of the final standard's provisions are stated in performance language, which is flexible enough to accommodate differences in particular workplaces or industries.

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For example, approved fit test systems, both quantitative and qualitative, are portable and can be used on construction work sites as well as in fixed industrial facilities. Another example is the final rule's requirement for medical surveillance; the frequency of medical reevaluation is now event driven, which will greatly simplify evaluations for employees who frequently change employment, as is the case with many construction workers. Thus, OSHA believes that the final rule is responsive to the Committee's concerns about the uniqueness of the construction industry and is sufficiently flexible to be used on worksites in this sector.

D. Assigned Protection Factors

OSHA is reserving the sections of this standard addressing assigned protection factors (APFs) pending further rulemaking. OSHA is working diligently to complete the reserved portions of the standard. In the interim, OSHA expects employers to take the best available information into account in selecting respirators. As it did under the previous standard, OSHA itself will continue to refer to the NIOSH APFs in cases where it has not made a different determination in a substance-specific standard.

E. Small Business Considerations

Pursuant to 5 U.S.C. 605(b) of the Regulatory Flexibility Act, OSHA certified to the Small Business Administration that the proposed respiratory protection standard would not have a significant impact on a substantial number of small entities.

For the purposes of fulfilling the requirements of the Regulatory Flexibility Act, the Agency in its Preliminary Regulatory Impact Analysis (PRIA) [Ex. 57] examined the impact of the standard on a number of different small establishment-size classes (1-7 employees, 8-19 employees, etc). Although some economies of scale associated with the proposed standard were noted, the Agency found that, given the modest costs per establishment and the limited impact of the proposed regulatory revisions as a whole, the standard would not impose a significant economic impact on a substantial number of small entities. These findings were summarized in the NPRM (59 FR 58894). At the time that OSHA published the NPRM for this rulemaking (Nov. 15, 1994), the Agency transmitted the certification setting forth this conclusion, along with the full PRIA, to the Small Business Administration.

In developing the final standard, the Agency has conducted a screening analysis to identify any significant impacts on a substantial number of small entities. The details of the screening analysis are presented in the Final Economic Analysis, which is available in the docket; a summary of the analysis appears in section VI. Based on this screening OSHA has again determined that the final rule will not impose a significant impact on a substantial number of small entities. The costs of the standard will equal no more than 0.02 percent of revenues for small firms in any affected industry, and will therefore pose no threat of business disruption, whether these costs are absorbed by affected firms or passed on to consumers. OSHA therefore certifies that the final rule will not have a significant impact on a substantial number of small entities.

Nevertheless, the Agency has designed the standard to minimize impacts on all affected establishments, and particularly on small entities. OSHA's special consideration of small businesses is in accord with the Agency's continuing policy to remain sensitive to the needs of small entities affected by Agency regulations.

Provisions that recognize the special needs of small businesses are discussed in more detail under specific sections of the Summary and Explanation of the standard, Section VIII. Examples of provisions where consideration was given to small businesses in making

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regulatory decisions include:

- Reduction in the number of repeat fit tests required for quantitative fit testing;
- Allowing employers to use a questionnaire (Appendix C is an example) as a minimal medical evaluation tool to ascertain an employee's ability to use respirators, rather than requiring a hands-on physical examination;
- Allowing medical evaluations to be conducted either by a physician or by another licensed health care professional (PLHCP), which will reduce medical surveillance costs without compromising employee protection;
- Making the frequency of medical evaluations, after the initial assessment, event-related instead of time-related, e.g., only requiring such evaluations when specific conditions indicate a need for a reevaluation;
- Reducing the amount of paperwork required in connection with medical evaluations. OSHA's previous standard required a physician to determine pertinent health and physical conditions, and further required that the respirator user's medical status be reviewed periodically (for instance, annually). Historically, employers have had physicians evaluate their employees' physical conditions, and have maintained records documenting those evaluations;
- Revising the requirements for disinfecting respirators from "after each use" to "as necessary to be maintained in a sanitary condition" to allow flexibility for small businesses;
- Requiring only that tags be used to document respirator inspections, rather than requiring written records; and
- Allowing the employer to obtain a certificate of analysis of breathing gas from the supplier rather than requiring employers to conduct gas analyses themselves.

In the Small Business Administration's *Annual Report to Congress*, a summary of SBA's comments to the respirator docket (Ex. 54-318) was provided. (Note that these comments pertain to the proposed rather than final rule.) SBA's comments have been examined alongside others with regard both to the proposal and its supporting economic analysis. As indicated, many of SBA's suggestions have been adopted; the SBA's comments on the Preliminary Regulatory Impact Analysis are discussed in detail in the economic impact chapter of the Final Economic Analysis.

Revised 29 CFR 1910.134 is intended to serve as a "building block" standard with respect to future standards that may contain respiratory protection requirements; that is, future standards that regulate respirator use in controlling employee exposure to hazardous conditions will refer to provisions in the final respiratory protection standard. Further, OSHA has found that the respirator provisions of existing substance-specific standards (Asbestos, Cadmium, Lead, etc.) were especially in need of revision in view of newly revised Sec. 1910.134. Except for a limited number of respirator provisions unique to each substance-specific standard, the remaining regulatory text on respirators now reads virtually the same for each of these standards. For example, all provisions addressing respirator use, selection, and fit testing were deleted from the substance-specific standards, making these standards consistent with the final respiratory protection standard with respect to these requirements. The Agency believes that the revisions being made to 29 CFR 1910.134 are sufficiently comprehensive to allow deletion of those provisions in the substance-specific standards that duplicated provisions in the revised final rule. A provision was retained only when it addressed conditions (for example, medical evaluation) that were unique and/or integral to

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the substance-specific standard.

The Agency concludes that deletion of duplicative provisions from the substance-specific standards will enhance compliance, especially for small businesses, and will thus will improve the protection afforded to employees who use respirators.

[63 FR 1152, January 8, 1998]

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DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Parts 1910, 1915, and 1926

[Docket No. H049]

RIN 1218-0099

Respiratory Protection

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Notice of proposed rulemaking (NPRM) and public hearings.

SUMMARY: OSHA is proposing to modify its existing standards on respiratory protection (29 CFR 1910.134, 29 CFR 1915.152 and 29 CFR 1926.103). The current respirator standard was adopted from a voluntary consensus standard in 1971. Since that time, changes in methodology, technology, and approach related to respiratory protection have occurred, which OSHA's standard does not include. The purpose of this rulemaking is to update the current standard to reflect these changes so that employers will provide effective protection for employees who wear respirators.

The proposed standard includes requirements for a written respiratory protection program; procedures for selecting respirators; requirements for medical evaluation; procedures for fit testing; requirements for using respirators; procedures for maintaining respirators; training; criteria for evaluating program effectiveness. Public hearings are being scheduled to provide interested parties the opportunity to orally present information and data related to the issues raised by this proposed rule.

DATES: Written comments on the proposed standard must be postmarked on or before February 13, 1995. Notices of intention to appear at the informal public hearings on the proposed standard must be postmarked by January 27, 1995. Parties who request more than 10 minutes for their presentations at the informal public hearing and parties who will submit documentary evidence at the hearing must submit the full text of their testimony and all documentary evidence postmarked no later than February 13, 1995. The hearing will take

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